

REMARKS

Applicant wishes to thank the Examiner for the careful consideration given to this application. As agreed upon during the teleconference of March 25, 2009, Applicant this Supplementary Amendment replaces and corrects the defect of the Preliminary Amendment filed March 3, 2009. Entry of this Supplementary Amendment in its entirety is respectfully requested. Claims 8-18 and 20-31 are pending in this application. Claims 8-18 stand withdrawn, and claims 22-31 are new. No new matter has been added.

Objections to the Specification

The objections to the specification raised in the Office Action mailed October 3, 2008 have been withdrawn pursuant to the Advisory Action mailed December 24, 2008.

Claim Objections

By virtue of the amendments to the specification entered pursuant to the Advisory Action mailed December 24, 2008, the terms “SC-01MFP” and “SC-02MFP” are consistent in the specification and pending claims. Accordingly, the Examiner’s objection is rendered moot.

35 U.S.C. § 102

Claim 20 stands rejected under 35 U.S.C. § 102(b) over Pene et al., Oncogene, 21:6587-6597 (2002) (“Pene”), and claim 21 stands rejected under 35 U.S.C. § 102(b) over Hata et al., Clin. Exp. Immunol., 94:370-375 (1994) (“Hata”). The Examiner states that Pene describes the “RPMI8226” cell line and Hata describes the “KMS-12BM” cell line and alleges that Applicant has failed to disclose a method of preparing SC-02MFP cells from RPMI8226 and SC-01MFP cells from KMS-12BM cells that would yield a structurally different established cell strain from the original cell strain. Applicant respectfully disagrees.

First and foremost, independent claim 20 is directed to SC-02MFP cells and not SC-01MFP cells as stated by the Examiner (Final Office Action, pg. 4). SC-02MFP cells of independent claim 20 were derived from the KMS-12BM cell strain, and SC-01MFP cells of independent claim 21 were derived from the RPMI8226 cell strain (specification, bottom of page 8). Accordingly, Applicant will address the Examiner’s rejection of claim 20 as being against claim 21 and vice versa.

As described in the Response filed December 3, 2008, the specification as filed describes the method by which SC-02MFP cells are prepared from KMS-12BM cells and SC-01MFP cells are prepared from RPMI8226 cells by inducing mutation in a medium including nitrosoguanidine (pg. 7, bottom) and selecting clones having high proliferation characteristics, diluting selected clones and reselecting for clones having high proliferation characteristics (pg. 8, 1st para.). Applicant respectfully asserts that selecting clones after any amount of a mutagenesis based on a specific characteristic (*e.g.*, high proliferation) distinguishes the mutated species from the original strain.

However, in order to facilitate allowance of the pending claims, Applicant respectfully submits the Declaration of Hiroharu Kawahara attached hereto, which provides experimental data demonstrating structural and functional differences between the KMS-12BM and SC-02MFP. In particular, Fig. 1 shows gamma chain production of SC-02MFP cells (closed squares) and its parent strain KMS-12BM (open squares) and SC-01MFP cells (closed circles) and its parent strain RPMI8226 (open circles). These data show that both SC-02MFP and SC-01MFP cells were able to maintain gamma chain production at relatively high levels for at least 300 days (~10 months), while KMS-12BM and RPMI8226 cells transfected and cultured under the same conditions were unable to maintain gamma chain production at such levels for an extended period of time. Furthermore, Fig. 2 shows that SC-02MFP cells (closed squares) and SC-01MFP cells (closed circles) are capable of growing to a higher cell density than either KMS-12BM (open squares) or RPMI8226 (open circles) in serum free medium illustrating another difference between the two strains.

Applicant respectfully submits that these data conclusively distinguish the SC-02MFP cells of independent claim 20 and the SC-01MFP cells of independent claim 21 from their parent strains, KMS-12BM, as described in Hata and RPMI8226 as described in Pene and provide clear evidence of a structural and functional difference between Applicant's claimed cell cultures and those described by Hata and Pene. Accordingly, Hata and Pene fail to anticipate independent claims 20 and 21, respectively, and withdrawal of the Examiner's rejection is respectfully requested.

New Claims

New claims 22-28 are product-by-process claims describing cells produced by a method substantially similar to the method used for the production of the SC-02MFP and SC-

01MFP cells of independent claims 20 and 21 and are allowable for at least the same reasons as independent claims 20 and 21. Support for these claims can generally be found throughout the specification and, in particular, on pages 5-8 of the specification as filed. Accordingly, allowance of claims 22-28 is respectfully requested.


New claims 29-31 describe a human cell strain having the unique characteristics similar to those of Applicant's claimed SC-02MFP and SC-01MFP cell strains. Accordingly, allowance of new claims 29-31 is respectfully requested for at least the same reasons as claims 20 and 21.

CONCLUSION

Payment for the extra claims presented herein are submitted with this response. In the event that an additional fee is required for this response, the Commissioner is hereby authorized to charge such fees to Deposit Account No. 50-0436.

Applicant believes that this application is in condition for allowance. However, should the Examiner have any questions or comments, or need any additional information from Applicant's attorney, please contact the undersigned attorney at your convenience.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'JMS', with a long horizontal flourish extending to the right.

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